

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte RICHARD JENKINS, JAMES P. GALVIN, HELEN SCHNEIDER,  
and RICHARD L. EGAN

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Appeal No. 1999-1326  
Application No. 08/413,294

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ON BRIEF

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Before ROBINSON, SCHEINER, and MILLS, Administrative Patent Judges.

ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 - 16, which are all of the claims pending in this application.

### REPRESENTATIVE CLAIMS

Claims 1 and 7, which are illustrative of the subject matter on appeal, read as follows:

1. A flat pouch for holding a reagent strip said pouch having proximal and distal ends and said reagent strip having a flat configuration with a pad sized to fit on the tongue to sample oral fluid, said pouch comprising:

a chamber and a first seal at said proximal pouch end on said pouch and a second seal distal to said first seal; and

said second seal stronger than said first seal.

7. In combination:

a reagent pad and a reagent strip having a flat configuration with a pad sized to fit on the tongue to sample oral fluid; and

a chamber and a pouch with proximal and distal ends having a first seal at said pouch proximal end and a second seal distal said first seal; and

said second seal stronger than said first seal,

and further comprising a collar capable of having a third seal proximal to said first seal, wherein said pad is insertable into said pouch by breaking said first seal.

### THE REFERENCE

Appeal No. 1999-1326  
Application No. 08/413,294

The reference relied on by the examiner is:

Mull	4,387,725	June 14, 1983
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### THE REJECTION

Claims 1 - 16 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over Mull.

On consideration of the record, we reverse this rejection.

### DISCUSSION

As stated in In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990), “[r]ejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all the elements of the claimed invention be described in a single reference.” As indicated above, claim 1, as well as claims 2 - 6 and 14, require a flat pouch. Similarly, claim 7, as well as claims 8 – 12 and 15 – 16, require that the reagent strip has a flat configuration. Here, the examiner has not established that Mull describes either a “flat” pouch or a reagent strip with a “flat configuration” as required by claims 1 and 7, respectively. To the extent that the examiner urges that “[t]he Mull disclosure is deemed to broadly encompass the instant limitation drawn to a ‘flat’ pouch and a reagent pad with a ‘flat configuration’ because Mull teaches a device in the form of an elongated and flexible plastic tube, which may be

depressed and form a 'flat' configuration" (Answer, page 4), we note, simply, that we find no explicit description in Mull of depressing either the flexible plastic tube into a flat pouch or the reagent strip into a flat configuration. Thus, Mull does not describe all of the elements of the claimed invention. Therefore, the examiner has failed to demonstrate that Mull anticipates the claimed invention within the meaning of 35 USC § 102(b).

Furthermore, with regard to the § 103 aspect of the rejection, the examiner has not explained why a person of ordinary skill would have been led from "here to there," i.e., from the elongated and flexible plastic tube of Mull to the "flat pouch" of claim 1 or the reagent strip with a "flat configuration" of claim 7. We find nothing in Mull which would have reasonably suggested a modification of the flexible plastic tube or the swab type collector described therein in a manner to arrive at the claimed invention. The fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Here, the examiner has not provided those facts or evidence which would have suggested the modifications of the pouch and reagent strip and pad described by Mull, in a manner to arrive at the claimed invention. Thus, in our opinion, the

examiner has failed to establish a prima facie case of obviousness within the meaning of 35 USC § 103 of the subject matter of the claims. Therefore, we reverse the rejection of claims 1 – 16 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over Mull.

#### Other Issues

Upon return of this application to the examining group, we would urge the examiner to step back and reconsider the relevance of U. S. Patent 3,915,806, issued October 28, 1975 to Horlach. This patent is of record in the case and was included with the Information Disclosure Statement filed September 30, 1996 (Paper No. 9) and would reasonably appear to disclose “a disposable kit for collecting, holding and transporting biological specimens” (Abstract) “in a flat elongated resilient pouch” (col. 1, lines 50-51) wherein “[a] sealed chamber containing a culture transport medium is formed at the lower end of one of the compartments, preferably by joining the two sheets along a transverse line extending across the compartment. The upper end of the sealed chamber is adapted to be easily ruptured.” (Col. 1, lines 57-62). Horlack states that, after the sample is collected, the swab “is reinserted into the compartment having the chamber at its lower end and thrust through the rupturable closure and into the

transport medium.” (Col. 2, lines 4-7). This disclosure is further embodied by the description of Figure 1, at column 2, line 57 – column 3, line 26. The disclosure of Horlack would appear to be particularly relevant to appealed claim 1.

We would interpret claim 1 to be directed to a flat pouch, which is capable of holding a reagent strip, having proximal and distal ends and having a chamber and a first seal and second seal wherein the second seal is stronger than the first seal. The specification, at page 3, indicates that :

“[t]he first seal, located proximally to the user, enables a preservative which is maintained within the pouch to be sealed during shipment of the pouch to the user. Thereafter, the user punctures the first seal upon placement of the reagent pad into the pouch.”

Also as stated at page 10 of the specification: “The upper temporary seal breaks when the user inserts the sample collection device into the pouch.” We note that claim 1 does not require the presence of the reagent strip (compare claim 7) and does not require the collar capable of forming a third seal proximal to the first (compare claim 6). The flat pouch described by Horlack would reasonably appear to explicitly describe all the elements of the claimed invention of at least claim 1 in a single reference.

We leave to the examiner, in the first instance, to determine whether claim 1 and possibly other claims pending in the application are subject to rejection based on the disclosure of Horlack. Such a determination should begin with an interpretation of each of the claims. We note, for example, that claim 1 requires that the pouch be capable of holding a “reagent strip” having a flat configuration. It is not readily apparent whether the “reagent pad” required by claims 3 and 4 must also have a flat configuration. To the extent that the examiner determines that the reagent pad of claims 3 and 4 do not have to be in a flat configuration, the disclosure of Horlack, which would appear to describe a swab type pad, may also be relevant to the patentability of these claims. It is this type of claim analysis which is necessary to appropriately determine whether there is reasonable basis for rejecting the claims of the application.

#### SUMMARY

The examiner’s decision rejecting claims 1 – 16 is reversed.

Appeal No. 1999-1326  
Application No. 08/413,294

REVERSED

Douglas W. Robinson	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Toni R. Scheiner	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Demetra J. Mills	)	
Administrative Patent Judge	)	

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